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Dkt. 0575/59167-A-PCT-US/JPW/BJA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : David J. "Pinsky"
U.S. Serial No. : 10/049,320 Examiner: S.-L. Chen
Filed : August 13, 1999 Group Art Unit: 1632
For : CD39/ECTO-ADPase FOR TREATMENT OF
THROMBOTIC AND ISCHEMIC DISORDERS

1185 Avenue of the Americas
New York, New York 10036
July 19, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with his duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit A**). References 1-44 were previously cited in connection with the prosecution of U.S. Serial Number 09/374,586 from which the subject application claims benefit under 35 U.S.C. §120. According to 37 C.F.R. §1.98(d), copies of patents or publications that were previously cited by, or submitted to, the Office in connection with such prior applications need not accompany the Information Disclosure Statement. Accordingly, copies of references 1-44 are not attached to this Information Disclosure Statement. A copy of reference no. 45 is attached hereto as **Exhibit B**.

- 1) Steering Committee, Lancet, (1986) "A Randomised, Blinded Trial of Clopidogrol versus Aspirin in

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- 3) Gura, T., (1997), "Systems for Identifying New Drugs are Often Faulty" *Science* 278:1041-1042;
- 4) Skolnick, J., et al. (2000) "From Genes to Protein Structure and Function: Novel Applications of Computational Approaches in the Genomic Era" *TIBTECH* 18:34-39;
- 5) Rudinger, J. (1976) "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence, *Peptide Hormones* 1-7;
- 6) Kaye, F.J., et al., (1990) "A Single Amino Acid Substitution Results In a Retinoblastoma Protein Defective in Phosphorylation and Oncoprotein Binding" *P.N.A.S.* 87:6922-6926;
- 7) Choudri et al. (1998). "Reduced microvascular thrombosis and improved outcome in acute murine stroke by inhibiting GP IIb/IIIa receptor-mediated platelet aggregation" *J. Clin. Invest.* 102(7):1301-1310;
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- 9) International Search Report for International Application No. PCT/US00/22060, November 14, 2000;
- 10) GenCore Accession No. WO4334,29 December 1996, BEAUDIOIN et al., WO96/32471 A2 (Univ. Sherbrooke) 17 October 1996;
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- 12) Kaczmarek, et al., (1996) "Identification and Characterization of CD39/Vascular ATP Diphosphohydrolase" *The Journal of Biological Chemistry* 271(51):33116-33122;
- 13) Bowie E. J. W., et al., (1974) "The Bleeding Time" Progress in & Hemostasis and Thrombosis, Spaet TH (ed.) 2d Ed, New York, Grune Statton, pp. 249-271;
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- 16) Buchanan M. R., et al., (1995) "Individual variation in the ASA effects of ASA on platelet function: Implication for the use of clinically" *Cardiovasc. Medicine* 11(3):221-227;
- 17) Chiu, D., et al., (1998) "Intravenous tissue plasminogen activator for acute ischemic stroke: feasibility, safety, and efficacy in the first year of clinical practice" *Stroke* 29: 18-22;
- 18) Choudhri, T. F., et al., (1997) "Use of a spectrophotometric hemoglobin assay to objectively quantify intracerebral hemorrhage in mice" *Stroke* 28:2296-2302;
- 19) Connolly, E. S. Jr., et al., (1996) "Cerebral protection in homozygous null ICAM-1 mice after middle cerebral artery occlusion. Role of neutrophil adhesion in the pathogenesis of stroke" *J. Clin. Invest.* 97:209-216;
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- 23) Eitzman D. T., (1996) "Bleomycin-induced pulmonary fibrosis in transgenic mice that either lack or overexpress the murine plasminogen activator inhibitor-I gene" *J. Clin. Invest.* 97:232-237;
- 24) Erickson, L. A., et al., (1990) "Development of venous occlusions in mice transgenic for the plasminogen activator inhibitor-I gene" *Nature* 346:74-76;
- 25) Gayle, R. B., et al., (1998) "Inhibition of platelet function by recombinant soluble ecto-ADPase/CD39" *J. Clin. Invest.* 101:851-1859;
- 26) Grotenhuis, K. H., (1991) "Effects of acetylsalicylic acid in stroke patients; evidence of nonresponders in a subpopulation of treated patients" *Thrombosis Res.* 63:587-593;
- 27) Handa, M., & Guidotti, G., (1996) "Purification and Cloning of a Soluble ATP-Diphosphohydrolase (Apyrase) from Potato Tubers (*Solanum tuberosum*)" *Biochem. Biophys. Res. Commun.* 218:916-923;
- 28) Harbison, J. W., (1998) "Clinical considerations in selecting Pharm antiplatelet therapy in cerebrovascular disease", *Am. J. Health Syst.* 55:S17-S20;

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- 29) Hechler, B., et al., (1998) "The P2Y1 receptor, necessary but not the sufficient to support full ADP-induced platelet aggregation, is not target of the drug clopidogrel" *Br. J. Haematol.* 3:858-866;
- 30) Huang, Z., et al., (1994) "Effects of Cerebral Ischemia in Mice Deficient Neuronal Nitric Oxide Synthase" *Science* 265:1883-1885;
- 31) Koch, R., Verhandlungen des X. Internationalem Medizinischen Congresses Berlin 1:35-47 (1891). (Abstract);
- 32) Lawson C. A., et al., (1997) "Monocytes and tissue factor promote 99: thrombosis in a murine model of oxygen deprivation", *J. Clin. Invest.*, 1729-1738;
- 33) Maeda K, et al., (1998) "Differences in the cerebrovascular anatomy of C57black/6 and SV129 mice" *Neuroreport* 9(7):1317-1319;
- 34) Majid A., et al., (1999) "Intrinsic, hemodynamic-independent differences in vulnerability to permanent focal cerebral ischemia in common mutant mouse strains", 24th American Heart Association International Conference on Stroke and Cerebral CXJO-XXPY;
- 35) Maliszewski, C. R., et al., (1994) "The CD39 lymphoid cell activation antigen: Molecular cloning and structural characterization" *J. Immunol.* 153:3574-3583;

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- 36) Marcus, A. J., & Safeir, L. B., (1993) "Thromboregulation: multicellular modulation of platelet reactivity in hemostasis and thrombosis" *FASEB J.* 7:516-522;
- 37) Marcus, A. J., (1999) "Platelets: Their role in hemostasis, thrombosis, and inflammation", In *Inflammation: Basic Principles and Clinical Correlates* (EDS Gallin, J.I. & Snyderman, R.: 77-95 (Lippincott, Williams & Wilkins, Philadelphia;
- 38) Marcus, A. J., et al., (1997) "The endothelial cell ecto-ADPase responsible for inhibition of platelet function is CD39" *J. Clin. Invest.* 99:1351-1360;
- 39) Marcus, A. J., et al., (1991) "Inhibition of platelet function by an aspirin-insensitive endothelial cell ADPase" *J. Clin. Invest.* 88:1690-1696;
- 40) Mayadas, T. N., et al., (1993) "Leukocyte rolling and extravasation are severely compromised in P-selection deficient mice" *Cell* 74(3): 541-554;
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- 42) Naka, Y., et al., (1995) "Enhanced preservation of orthotopically transplanted rat lungs by nitroglycerin but not hydralazine: Requirement for

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vasodilation" *Circ. Res.* 76:900-906;

- 43) Schoenborn, M. A., et al., (1998) "Gene structure and chromosome location of mouse Cd39 coding for an ecto-apyrase", *Cytogen. Cell Gen.*, 81(3-4):287-280;
- 44) Wardlaw, J. M., et al., (1997) "Systematic review of evidence on thrombolytic therapy for acute ischemic stroke" *Lancet.* 350:607-614; and
- 45) U.S. Patent Application Publication No. 2002/0138858, published September 26, 2002. (Exhibit B)

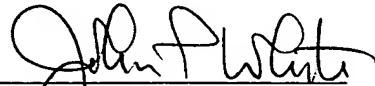
This Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(b). Applicant requests that the Examiner review the publications and make them of record in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. If any such fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:	
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Form PTO-1449 <i>PE</i> <i>21 JAN 2004</i> <i>TRADEMARK OFFICE</i>		U.S. Department of Commerce Patent and Trademark Office			Atty. Docket No. 0575/59167-A-PCT-US /JPW/BJA		Serial No. 10/049,320	
		INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)			Applicant: David J. Pinsky			
					Filing Date: February 6, 2002		Group Art Unit 1632	
U.S. PATENT DOCUMENTS								
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
		Steering Committee, Lancet, (1986) "A Randomised, Blinded Trial of Clopidogrol versus Aspirin in Patients at Risk of Ischaemic Events" CAPRIE 348:1329-1339						
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		Rudinger, J. (1976) "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence, Peptide Hormones 1-7						
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	Kaczmarek, et al. (December 1996) Identification and Characterization of CD39/Vascular ATP Diphosphohydrolase, The Journal of Biological Chemistry. 271(51) :33116-33122;

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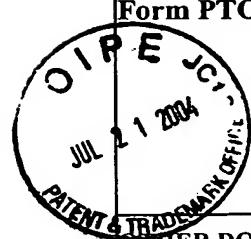
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	Huang, Z., et al., (1994) "Effects of Cerebral Ischemia in Mice Deficient Neuronal Nitric Oxide Synthase" <i>Science</i> 265:1883-1885;
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		Naka, Y., et al., (1995) "Enhanced preservation of orthotopically transplanted rat lungs by nitroglycerin but not hydralazine: Requirement for graft vascular homeostasis beyond harvest vasodilation" <i>Circ. Res.</i> 76:900-906;
		Schoenborn, M. A., et al., (1998) "Gene structure and chromosome location of mouse Cd39 coding for an ecto-apyrase", <i>Cytogen. Cell Gen.</i> , 81(3-4):287-280;
		Wardlaw, J. M., et al., (1997) "Systematic review of evidence on thrombolytic therapy for acute ischemic stroke" <i>Lancet.</i> 350:607-614; and
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